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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	24

DATE MAILED: 06/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/530,772	BRAHMBHATT ET AL.	
	Examiner	Art Unit	
	Arun Chakrabarti	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Continued Examination Under 37 CAR 1.114

1. A request for continued examination under 37 CAR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CAR 1.114, and the fee set forth in 37 CAR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CAR 1.114. Applicant's submission filed on May 6, 2002 has been entered.

Specification

2. Claims 1, 6, 8-10, 15, 17, and 19 have been amended and new claims 20-21 have been added.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 2, 6, and 13-21 are rejected under 35 U.S.C. 103 (a) over Herrero et al. (Journal of Bacteriology, (1990), Vol. 172, No. 11, pages 6557-6567) in view of Harley et al. (U.S. Patent 5,863,726) (January 26, 1999).

Herrero et al. teach a suicide expression vector for expressing heterologous peptide, polypeptide or protein in a selected host cell (Abstract), the vector comprising :

(I) a first nucleotide sequence encoding the heterologous peptide, polypeptide or protein operably linked to a first promoter sequence (Figure 3, Figure 7 and Page 6500, column 1, Construction of arsenite resistance cassette subsection) ;

(ii) a second nucleotide sequence encoding a restriction enzyme (transposase) or functional portion thereof operably linked to a second promoter (lac) sequence, the second promoter sequence being inducible (Figures 2 , 3 and 7); and

(iii) one or more cleavage site(s) for the restriction enzyme or functional portion thereof, the cleavage site(s) being absent from the chromosomal DNA of the host cell (Tn5-site in Figures 2 and 7).

Herrero et al. teach a suicide expression vector wherein the first nucleotide sequence encodes a protein (Figure 3, Figure 7 and Page 6500, column 1, Construction of arsenite resistance cassette subsection).

Herrero et al. teach a bacterium host cell transformed with a suicide expression vector (Abstract and Figure 9).

Herrero et al. teach a method of expressing a heterologous peptide, polypeptide or protein in a selected host cell (Abstract, Figure 3 and Results and Discussion Section), comprising:

(I) transforming the bacterium host cell with a suicide expression vector (Figure 9);

(ii) culturing the transformed host cell under suitable conditions for the expression of the heterologous peptide, polypeptide or protein (Figure 9 and Tn5- based transposon vector delivery system, page 6562, column 2) .

Herrero et al. teach a method for the production of a microorganism vector which contains recombinant peptide, polypeptide or protein but no recombinant DNA (Abstract and Figure 9B), comprising:

(I) transforming the bacterium host cell with a suicide expression vector (Figure 9B);

(ii) culturing the transformed host cell under suitable conditions for the expression of the heterologous peptide, polypeptide or protein (Figure 9B).

Herrero et al. teach a method wherein the microorganism is a bacterium (Abstract).

Herrero et al. teach a suicide expression vector wherein the second nucleotide sequence encodes a restriction enzyme that recognize a cleavage site(s) of ten or more nucleotides (Figure 7).

Herrero et al teach the cleavage and degradation of the vector by inducing expression of the transposase enzyme or functional portion thereof (Abstract and Figure 7).

Herrero et al do not teach the cleavage and degradation of the vector by inducing expression of the restriction enzyme or functional portion thereof.

Harley et al. teach the cleavage and degradation of the vector by inducing expression of the restriction enzyme or functional portion thereof (Column 8, lines 56).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the cleavage and degradation of the vector by inducing expression of the restriction enzyme or functional portion thereof of Harley et al. with the suicide expression vector of Herrero et al. since Harley et al state, "Such a plasmid substrate is particularly useful for in situ applications (Column 8, lines 38-39)". Furthermore, this is also obvious that transposase gene may not be required to be integrated in the vector when transpositions are not needed in different location of the chromosomes and may be substituted with customized restriction enzyme of choice. An ordinary practitioner would have been motivated to substitute and combine the cleavage and degradation of the vector by inducing expression of the restriction enzyme or functional portion thereof of Harley et al. with the suicide

expression vector of Herrero et al., in order to achieve the express advantages, as noted by Harley et al., of a plasmid substrate which is particularly useful for in situ applications.

4. Claims 1, 2, 6-8, and 13-21 are rejected under 35 U.S.C. 103 (a) over Herrero et al. (Journal of Bacteriology, (1990), Vol. 172, No. 11, pages 6557-6567) in view of Harley et al. (U.S. Patent 5,863,726) (January 26, 1999) further in view of Marshall et al. (U.S. Patent 5,420,032) (May 30, 1995).

Herrero et al in view of Harley et al. teach the suicide vector of claims 1, 2, 6, and 13-21 as described above.

Herrero et al in view of Harley et al do not teach the suicide vector wherein the second nucleotide sequence encodes a restriction enzyme selected from I-CeuI.

Marshall et al. teach the suicide expression vector wherein a nucleotide sequence encodes a restriction enzyme selected from I-CeuI (Abstract, Figures 1-9 , Examples 1 and Columns 17-18).

Herrero et al. in view of Harley et al do not teach a suicide expression vector wherein the one or more cleavage site(s) are located at site(s) on the vector which avoids steric hindrance of binding by the restriction enzyme.

Marshall et al. teach a suicide expression vector wherein the one or more cleavage site(s) are located at site(s) on the vector which avoids steric hindrance of binding by the restriction enzyme.(Figures 1, 3 and 5).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the nucleotide sequence encoding a restriction enzyme selected from I-CeuI of Marshall et al. with the suicide expression vector of Herrero et al. in view of Harley et al since Marshall et al state, "All of the above results demonstrate that naturally occurring or synthetic substrates bearing base-pair substitutions (degenerate DNA sequence) can be recognized and cleaved by I-CeuI, a novel homing endonuclease, which will be useful as a "restriction" enzyme for cleaving low frequency sequence, because of its long recognition sequence (Column 18, lines 62-68)". Furthermore, this is also obvious that transposase gene may not be required to be integrated in the vector when transpositions are not needed in different location of the chromosomes and may be substituted with customized restriction enzyme of choice. An ordinary practitioner would have been motivated to substitute and combine the nucleotide sequence encoding a restriction enzyme selected from I-CeuI of Marshall et al. with the suicide expression vector of Herrero et al. in view of Harley et al , in order to achieve the express advantages, as noted by Marshall et al., of a novel homing endonuclease, which will be useful as a "restriction" enzyme for cleaving low frequency sequence, because of its long recognition sequence.

5. Claims 1, 2, 3, 6, 7, and 13-21 are rejected under 35 U.S.C. 103 (a) over Herrero et al. (Journal of Bacteriology, (1990), Vol. 172, No. 11, pages 6557-6567) in view of Harley et al. (U.S. Patent 5,863,726) (January 26, 1999) further in view of Hardy et al. (U.S. Patent 5,851,817) (December 22, 1998).

Herrero et al. in view of Harley et al teach suicide expression vector of claims 1, 2, 6, and 13-21 as described above.

Herrero et al. in view of Harley et al. do not teach the suicide expression vector wherein the first nucleotide sequence encodes a contraceptive antigen.

Hardy et al. teach the suicide expression vector wherein the first nucleotide sequence encodes a contraceptive antigen (Abstract, Figure 10 and Example II).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the contraceptive antigen of Hardy et al. with the suicide expression vector of Herrero et al. in view of Harley et al since Hardy et al state, "Also disclosed are methods for speciating mammalian eggs, identifying species-specific sperm, and proving contraception in a mammalian population. Specifically disclosed are nucleic acid sequences and the corresponding amino acid sequences of specific sperm membrane proteins they encode, whose identification and characterization have permitted development of species-specific contraceptive and fertility compositions and methods (Abstract)". An ordinary practitioner would have been motivated to substitute and combine the contraceptive antigen of Hardy et al. with the suicide expression vector of Herrero et al. in view of Harley et al, in order to achieve the express advantages, as noted by Hardy et al., of a specific nucleic acid sequences and the corresponding amino acid sequences of specific sperm membrane proteins they encode, whose identification and characterization have permitted development of species-specific contraceptive and fertility compositions and methods.

6. Claims 1, 2, 4, 6, 7, and 13-21 are rejected under 35 U.S.C. 103 (a) over Herrero et al. (Journal of Bacteriology, (1990), Vol. 172, No. 11, pages 6557-6567) in view of Harley et al. (U.S. Patent 5,863,726) (January 26, 1999) further in view of Calvet et al. (U.S. Patent 5,552,313) (September 3, 1996).

Herrero et al. et al in view of Harley et al teach suicide expression vector of claims 1, 2, 6, and 13-21 as described above.

Herrero et al. in view of Harley et al do not teach the suicide expression vector wherein the first nucleotide sequence encodes an esterase capable of hydrolyzing organophosphates.

Calvet et al. teach the suicide expression vector wherein the first nucleotide sequence encodes an esterase capable of hydrolyzing organophosphates. (Abstract, Example 12 and Column 5, line 20 to column 6, line 67).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the nucleotide sequence encoding an esterase capable of hydrolyzing organophosphates of Calvet et al. with the suicide expression vector of Herrero et al. in view of Harley et al since Calvet et al state, "Knowledge of the mouse phosphotriesterase-related sequence will permit other mammalian genes and cDNAs to be isolated by using the mouse DNA as a hybridization probe to screen recombinant DNA libraries from other organisms, or by using an antibody to the mouse protein to screen protein expression libraries. Having genes or cDNAs from other organisms helps in determining the protein's functions and provide better reagents for human use (column 6, lines 7-14)". An ordinary

practitioner would have been motivated to substitute and combine the. nucleotide sequence encoding an esterase capable of hydrolyzing organophosphates of Calvet et al. with the suicide expression vector of Herrero et al. in view of Harley et al, in order to achieve the express advantages, as noted by Calvet et al., of a knowledge of the mouse phosphotriesterase-related sequence which will permit other mammalian genes and cDNAs to be isolated by using the mouse DNA as a hybridization probe to screen recombinant DNA libraries from other organisms, or by using an antibody to the mouse protein to screen protein expression libraries.

7. Claims 1, 2, 5, 6, 7, and 13-21 are rejected under 35 U.S.C. 103 (a) over Herrero et al. (Journal of Bacteriology, (1990), Vol. 172, No. 11, pages 6557-6567) in view of Harley et al. (U.S. Patent 5,863,726) (January 26, 1999) further in view of Kemp et al. (U.S. Patent 6,111,070) (August 29, 2000).

Herrero et al. in view of Harley et al teach suicide expression vector of claims 1, 2, 6, and 13-21 as described above.

Herrero et al. in view of Harley et al do not teach the suicide expression vector wherein the first nucleotide sequence encodes an insecticidal toxin.

Kemp et al. teach the suicide expression vector wherein the first nucleotide sequence encodes an insecticidal toxin.(Abstract, Figures 1-4 and Column 13, line 37 to column 14, line 50 and Example 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the nucleotide sequence encoding an

insecticidal toxin. of Kemp et al. with the suicide expression vector of Herrero et al. in view of Harley et al since Kemp et al state, "The introduction and expression of the structural gene for an insecticidal protein can be used to protect a crop from infestation with insect larvae of species which include, but are not limited to, hornworm, pink bollworm, European corn borer, tobacco budworm, and cabbage looper (Column 14, lines 25-31)". An ordinary practitioner would have been motivated to substitute and combine the. nucleotide sequence encoding an insecticidal toxin. of Kemp et al. with the suicide expression vector of Herrero et al. in view of Harley et al, in order to achieve the express advantages, as noted by Kemp et al., of a structural gene for an insecticidal protein which can be used to protect a crop from infestation with insect larvae of species which include, but are not limited to, hornworm, pink bollworm, European corn borer, tobacco budworm, and cabbage looper.

8. Claims 1, 2, 6, 7, 9 and 13-21 are rejected under 35 U.S.C. 103 (a) over Herrero et al. (Journal of Bacteriology, (1990), Vol. 172, No. 11, pages 6557-6567) in view of Harley et al. (U.S. Patent 5,863,726) (January 26, 1999) further in view of Barber et al. (U.S. Patent 6,043,077) (March 28, 2000).

Herrero et al. in view of Harley et al teach suicide expression vector of claims 1, 2, 6, and 13-19 as described above.

Herrero et al. in view of Harley et al do not teach the suicide expression vector wherein the third nucleotide sequence encodes a ribozyme targeted against specific mRNA.

Barber et al. teach the suicide expression vector wherein a nucleotide sequence encodes a ribozyme targeted against specific mRNA. (Abstract, Figures 1-3 , Examples 1-9 and Column 7, line 64 to column 8, line 16).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the nucleotide sequence encoding a ribozyme targeted against specific mRNA of Barber et al. with the suicide expression vector of Herrero et al. in view of Harley et al since Barber et al state, "These vectors provide the advantage of providing multi functional therapy against HCV infection, preferably with the various therapies working together in synergy (Column 8, lines 10-12)". An ordinary practitioner would have been motivated to substitute and combine the. nucleotide sequence encoding a ribozyme targeted against specific mRNA of Barber et al. with the suicide expression vector of Herrero et al. in view of Harley et al, in order to achieve the express advantages, as noted by Barber et al., of vectors which provide the advantage of providing multi functional therapy against HCV infection, preferably with the various therapies working together in synergy.

9. Claims 1, 2, 6, and 10-21 are rejected under 35 U.S.C. 103 (a) over Herrero et al. (Journal of Bacteriology, (1990), Vol. 172, No. 11, pages 6557-6567) in view of Harley et al. (U.S. Patent 5,863,726) (January 26, 1999) further in view of Paul et al. (U.S. Patent 6,291,741 B1) (September 18, 2001).

Herrero et al teach the vector of claims 1, 2, 6, and 13-21 as described above.

Herrero et al do not teach the vector, wherein the second promoter is selected from T7 RNA Polymerase promoter operably linked to an inducible third promoter.

Paul et al teach the vector, wherein the second promoter is selected from T7 RNA Polymerase promoter operably linked to an inducible third promoter (Column 15, lines 1-4).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the vector, wherein the second promoter is selected from T7 RNA Polymerase promoter operably linked to an inducible third promoter of Paul et al. with the suicide expression vector of Herrero et al. in view of Harley et al since Paul et al state, "Preferred genes are the Barnase ORF under control of a suitably modified T7 promoter, and a T7 RNA Polymerase gene under control of a promoter specific for tissues to be destroyed (Column 15, lines 1-4)". An ordinary practitioner would have been motivated to substitute and combine the vector, wherein the second promoter is selected from T7 RNA Polymerase promoter operably linked to an inducible third promoter of Paul et al. with the suicide expression vector of Herrero et al. in view of Harley et al., in order to achieve the express advantages, as noted by Paul et al., of preferred genes which are under control of a suitably modified T7 promoter, and a T7 RNA Polymerase gene under control of a promoter specific for tissues to be destroyed.

Response to Amendment

10. In view of the amendment, 112 (second paragraph) rejections and 102 (b) rejections are hereby withdrawn. However, new 103 (a) rejections are included.

Response to Arguments

11. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's declaration filed on May 6, 2002, have been fully considered but they are not persuasive. Although transposase and restriction enzymes are different, it is well known in the art that desired restriction enzyme site can be incorporated in the transposon area of the DNA of a suicide vector. This has been clearly shown by Tucker et al. (U.S. Patent 5,102,797) (April 7, 1992) (Column 5, lines 34-46). Furthermore, this is also obvious that transposase gene may not be required to be integrated in the vector when transpositions are not needed in different location of the chromosomes and may be substituted with customized restriction enzyme of choice

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

May 22, 2002

W. Gary Jones
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